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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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**CELGENE CORPORATION,**

**Plaintiff,**

**v.**

**BARR LABORATORIES, INC.,**

**Defendant.**

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) **Civil Action No. 07-286 (SDW)(MCA)**  
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) **Hon. Susan D. Wigenton, U.S.D.J.**  
) **Hon. Madeline C. Arleo, U.S.M.J.**  
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) **(Filed Electronically)**  
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**CELGENE CORPORATION'S MEMORANDUM IN SUPPORT OF  
ITS MOTION FOR LEAVE TO AMEND ITS COMPLAINT**

Celgene Corporation (“Celgene”) submits this memorandum in support of its motion for leave to amend its complaint.<sup>1</sup> Celgene’s proposed amended complaint alleges infringement of U.S. Patent Nos. 5,629,327 (“the ‘327 patent”) and 6,235,756 (“the ‘756 patent”) (collectively, “the cancer patents”) by Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively, “Barr”) based on their filing of their amended ANDA to sell a generic version of Celgene’s Thalomid® product.<sup>2</sup>

## **I. INTRODUCTION**

The timing of this motion is purely the product of Barr’s choosing. Barr has known about the ‘327 and ‘756 patents since at least September, 2006. Yet, it waited 20 months -- specifically, until May 21, 2008 -- to file a Paragraph IV certification against those two patents. That Paragraph IV filing is an act of patent infringement. It gives rise to the infringement claims (Counts IX-X) that are the subject of Celgene’s proposed amended complaint.

Because Barr’s act of patent infringement did not take place until after the deadline for amendment in this Court’s scheduling order (May 1, 2008), good cause exists for allowing amendment. Obviously, Celgene could not have known before that deadline that Barr would elect to subsequently file a Paragraph IV certification against the cancer patents that it had, at that time, known about for nearly 20 months. Moreover, Barr cannot claim that it will be prejudiced by amendment -- after all, Barr is responsible for the timing of the amendment. The original case is still in document discovery and no depositions have taken place. Thus, Celgene respectfully requests that its motion for leave to amend be granted.

## **II. FACTUAL BACKGROUND**

Children’s Medical Center Corporation (“CMCC”) is the owner of the ‘327 and ‘756 patents. Celgene is the exclusive licensee. These patents cover methods of administering

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<sup>1</sup> Celgene’s proposed Seconded Amended Complaint is attached hereto as Exhibit A.

<sup>2</sup> Copies of the ‘327 and ‘756 patents are attached hereto as Exhibits B and C.

thalidomide to prevent undesired angiogenesis. “Angiogenesis” refers to the generation of new blood vessels into a tissue or organ. Undesired angiogenesis occurs in multiple disease states, including tumors. Barr’s amended ANDA No. 78-505 seeks approval to market thalidomide for the uses covered by the ‘327 and ‘756 patents prior to those patents’ expiration. This constitutes an act of infringement under 35 U.S.C. 271(e)(2). Consequently, Celgene now seeks to amend its complaint to allege Barr’s infringement of these patents.<sup>3</sup>

The scheduling order in this case set a deadline of May 1, 2008 for amendments to pleadings. Celgene’s motion to amend is being made after that deadline due entirely to the actions of Barr. When a generic pharmaceutical company files an ANDA, it must include a statement concerning the status of any patents listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to branded product. *See* 21 U.S.C. §§ 355(j)(2)(A)(vii)-(viii). Here, Barr filed its ANDA in September, 2006. At that time, the Orange Book listed both the ‘327 and ‘756 patents. Yet, when Barr originally filed its ANDA, it told the FDA that it was not seeking an indication covered by those patents.

Because Barr told the FDA it was not seeking an indication covered by those patents, it was not required to certify that the ‘327 and ‘756 patents were invalid, unenforceable, and/or not infringed by Barr’s ANDA product. In other words, in 2006, Barr did not file a Paragraph IV certification against those patents. Consequently, when Celgene filed its original complaint, it did not assert those patents because Barr had not made a Paragraph IV filing against them.

However, on May 21, 2008, Barr apparently had a change of heart. On that date, twenty (20) months after it had first known about the cancer patents, Barr amended its ANDA that is the subject of this action by filing a Paragraph IV certification against those patents. Thus, for the first time, Barr certified to the FDA that the cancer patents were invalid, unenforceable, and/or not

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<sup>3</sup> Counsel for Celgene has sought Barr’s consent regarding this motion. Barr has not taken a position as to whether it will consent.

infringed by Barr's ANDA product. On May 22, 2008, Barr informed Celgene and CMCC of this certification, and its contention that those patents are invalid and unenforceable. Barr waited until this late date -- again 20 months after it filed its ANDA and three weeks after the deadline for amendment -- even though the cancer patents have been listed in the Orange Book since long before Barr had even contemplated filing an ANDA to market generic thalidomide. Thus, the timing of Celgene's amendment has been caused entirely by Barr's unilateral decision to wait until May 21, 2008 to certify against the cancer patents.

### III. LEGAL STANDARD

Ordinarily, motions for leave to file amended pleadings are governed by the standards of Rule 15 of the Federal Rules of Civil Procedure, which provides:

[A] party may amend the party's pleading only by leave of the court or by written consent of the adverse party; and *leave shall be freely given when justice so requires.* (emphasis added).

When a scheduling order sets a deadline for amending pleadings, however, Rule 16(b) is implicated and "good cause" must be shown to modify the scheduling order. *See Enzo Life Sciences, Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 487 (D. Del. 2003). The "good cause" standard must be read in conjunction with the Rule 15(a) standard that leave for amendment shall be "freely given." *Reynolds v. Borough of Avalon*, 799 F. Supp. 442, 450 (D.N.J. 1992). The Rule 15(a) standard is a liberal one:

Rule 15(a) declares that leave to amend "shall be freely given when justice so requires"; *this mandate is to be heeded....* In the absence of any apparent or declared reason -- such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc. -- the leave sought should, as the rule requires, be "freely given." (emphasis added).

*Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Howze v. Jones & Laughlin Steel Corp.*, 750 F.2d 1208, 1212 (3d Cir. 1984). Under these standards, Celgene's motion should be granted.

#### IV. ARGUMENT

Courts have found good cause to modify scheduling orders to allow amended pleadings where the facts and circumstance that gave rise to the amended claims occurred after the scheduled amendment deadline. *See Enzo*, 270 F. Supp. 2d at 490 (amended counterclaims based on documents produced by non-moving party after amendment deadline); *Reynolds*, 799 F. Supp. 2d at 450 (amendment based on deposition of non-moving party after deadline). Here, as described above, the timing of Celgene's motion is entirely attributable to Barr's late decision to amend its ANDA to include a certification against the cancer patents. Celgene filed its original complaint asserting only those patents that Barr had included in its initial notification letter. After its initial notification letter, Barr sent four "supplemental" notification letters concerning amendments to its ANDA. Barr's fourth supplemental notification letter -- sent after the pleadings amendment deadline -- for the first time included a certification against the cancer patents. Thus, Celgene had no knowledge of Barr's certification concerning the cancer patents until it received Barr's May 22, 2008 notification letter. Indeed, no such certification took place until May 21, 2008. Accordingly, good cause exists to allow amendment at this date.

Barr will suffer no prejudice if Celgene is granted leave to amend. The Third Circuit has repeatedly held that "prejudice to the non-moving party is the touchstone for the denial of amendment." *See, e.g., Cal. Pub. Empls'. Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 171 (3d Cir. 2004). For purposes of Rule 15, the term prejudice means undue difficulty in defending a lawsuit as a result of a change in theories on the part of *the other party*. *See Deakyne v. Comm'rs of Lewes*, 416 F.2d 290, 300 (3d Cir. 1969). Barr cannot claim that it will be prejudiced here, where the timing of Celgene's amended complaint is due entirely to Barr's unilateral decision to delay certifying against the cancer patents until after the deadline for pleading amendments.

Further, Barr will suffer no prejudice because discovery in this case is ongoing and Barr will have ample opportunity to take seek information concerning the cancer patents. The parties are currently in the midst of document production. In fact, to date, Barr has not even provided Celgene with a complete copy of its ANDA.

Also, to date, no depositions have been taken in this matter. Barr will have the opportunity to take depositions regarding the cancer patents. This is particularly true given that the cancer patents have a single inventor common to both patents. In addition, Celgene's amended infringement allegations relate to the same Barr ANDA that is already the subject of this litigation. Therefore, allowing amendment will not hamper Barr's ability to defend itself in any way.

**V. CONCLUSION**

For the reasons stated above, Celgene respectfully requests that its motion for leave to amend be granted.

Respectfully submitted,

Dated: July 3, 2008

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